

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

ANNETTE SUTPHIN,

Plaintiff,

v.

CIVIL ACTION NO. 2:14-cv-01379

ETHICON INC.

Defendant.

MEORANDUM OPINION AND ORDER

Pending before the court is a Motion for Summary Judgment, [ECF No. 25], filed by Defendant Ethicon Inc. (“Ethicon”). Plaintiff Annette Sutphin has responded, [ECF No. 31], and the Motion is ripe for adjudication. The Motion is **DENIED** for the reasons that follow.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”) Plaintiff Annette Sutphin is a resident of West Virginia. Pl.’s Short Form Compl. ¶ 4 [ECF No. 1]. Around January 2009, David Afram, M.D. diagnosed Ms. Sutphin with SUI, large cystocele, and mild uterine prolapse. In West Virginia, on February 24, 2009, she was implanted with a Tension-free Vaginal Tape-Obturator (“TVT-O”) device, manufactured by Defendant, to treat SUI. *Id.* at ¶ 10. Dr. Afram performed the

surgery. Since her implant, Plaintiff claims she has suffered mesh erosion, mesh exposure, mesh extrusion, mesh construction, scarring, dyspareunia, pelvic pain, vaginal pain, bleeding, recurrent stress urinary incontinence, urge incontinence, hematuria, recurrent vulvar/perineal cysts/lesions, infections, and chronic urinary tract infections (“UTIs”) as a result of the TVT-O. *See* Office Notes, Ex. 5 [ECF No. 31–5].

On January 13, 2014, Plaintiff filed a Short Form Complaint against Defendant alleging the following claims: Count I–negligence, Count II–strict liability (manufacturing defect), Count III–strict liability (failure to warn), Count IV–strict liability (defective product), Count V–strict liability (design defect), Count VI–common law fraud, Count VII–fraudulent concealment, Count VIII–constructive fraud, Count IX–negligent misrepresentation, Count X–negligent infliction of emotional distress, Count XI–breach of express warranty, Count XII–breach of implied warranty, Count XIII–violation of consumer protection laws, Count XIV–gross negligence, Count XV–unjust enrichment, Count XVII–punitive damages, Count XVIII–discovery rule and tolling.¹

II. Legal Standard

a. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to

¹ For clarity, I will note that Count XVI on the standard Short Form Complaint in this MDL claims loss of consortium. Plaintiff in this case does not allege Count XVI for loss of consortium. Pl.’s. Short Form Compl. ¶ 13 [ECF No. 1].

judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

The nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict” in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

b. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. Here, Plaintiff and Defendant agree that West Virginia substantive law applies to Ms. Sutphin’s claims because she underwent her TVT-O implant surgery and suffered the resulting injuries from that surgery in West Virginia. *See McKinney v. Fairchild Intern., Inc.*, 487 S.E.2d 913, 922 (W. Va. 1997) (“Traditionally, West

Virginia courts apply the *lex loci delicti* choice-of-law rule; that is, the substantive rights between the parties are determined by the law of the place of injury.”).

III. Discussion

a. Strict liability—design defect (Count V)

Defendant moves for summary judgment on Count V, strict liability—design defect, claiming Plaintiff failed to present sufficient evidence of (1) a feasible alternative design to the TVT-O or (2) that a defect in the TVT-O caused Ms. Sutphin’s injuries. I disagree.

To establish a design defect claim under a theory of strict liability, a plaintiff must present sufficient evidence that a product is defective and that the alleged defect proximately caused the plaintiff’s injuries. *See Morningstar v. Black and Decker Mfg. Co.*, 253 S.E.2d 666, 682–83 (W. Va. 1979). A product is defective when it is not reasonably safe for its intended use. *Id.* “In a West Virginia strict liability design defect products liability case, a plaintiff must prove that there was an alternative, feasible design—existing at the time of the product’s manufacture—that would have eliminated the risk that injured the plaintiff.” *Mullins v. Ethicon, Inc.*, No. 2:12-CV-02952, 2016 WL 7197441, at *5 (S.D.W. Va. Dec. 9, 2016). West Virginia law does not “require a plaintiff to show specific causation” as it relates to a design defect. *Id.* “Whether a product’s design is defective is an inquiry separate from causation.” *Id.* “Once the trier of fact determines that the plaintiff has satisfied the risk-utility test, the product’s design is considered defective as to the design feature singled-out by the

plaintiff.” *Id.* The plaintiff must then satisfy the “entirely separate issue of whether the defective design proximately caused the plaintiff’s injury.” *Id.*

In this case, Plaintiff has proffered evidence on various feasible alternative designs to TVT-O, including polyvinylidene fluoride (“PVDF”), and larger pore, lighter weight mesh. *See* Pls.’s Designation and Disclosure of Case-Specific Expert Witnesses, Ex. 9 [ECF No. 31–1]; Rule 26 Expert Report of Dr. Daniel Elliott, Ex. 10, 36–37 [ECF No 31–2]. It is sufficient to set forth evidence of an alternative design using general experts. *See Fox v. Ethicon, Inc.*, 2016 WL 3748509, at *3 (S.D. W. Va. July 8, 2016) (applying Texas law). Plaintiff has produced evidence that these purported safer alternative designs would have reduced Ms. Sutphin’s injuries, would not have affected the product’s utility, and would have been economically and technologically feasible. *See* Rule 26 Expert Report of Dr. Daniel Elliott, Ex. 10, 36–37 [ECF No 31–2]. Accordingly, the court **FINDS** that there remains a genuine dispute of material fact regarding the existence of a safer alternative design under West Virginia law. Defendant’s Motion for Summary Judgment on Plaintiff’s claim for strict liability design defect (Count V) is **DENIED**.

b. Failure to warn (Count III)

Under West Virginia law, a failure to warn cause of action “covers situations when a product may be safe as designed and manufactured,” but then “becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner.” *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603, 609 (W.Va.1983); *see also Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 502010, at *4 (S.D.W. Va. Feb. 5, 2015). To substantiate a failure to warn

claim under strict liability, the plaintiff must show that the failure to adequately warn “made the product not reasonably safe” and “that the defect was the proximate cause of her injuries.” *Id.* at 610. This duty to warn accounts for the knowledge of the likely user of a product. *See* W. Va. P.J.I. at § 414 (providing that in order to succeed on a failure-to-warn claim, a plaintiff must demonstrate that, inter alia, the use of the product “involves a substantial danger that would not be readily recognized by the ordinary user of the [product]”).

West Virginia applies the learned intermediary doctrine to cases involving prescription medical devices. *See Tyree v. Bos. Sci. Corp.*, 56 F. Supp. 3d 826, 832 (S.D.W. Va. 2014). In 2016, the West Virginia legislature explicitly codified the learned intermediary doctrine. *See* West Virginia Code § 55-7-30. “The learned intermediary doctrine stands for the proposition that a drug manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product’s dangers.” *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 502010, at *4 (S.D.W. Va. Feb. 5, 2015) (applying West Virginia law).

Here, Plaintiff argues that the learned intermediary doctrine does not apply because the statute was enacted after “all the pertinent events regarding Ms. Sutphin’s claims, including Defendants’ issuance of warnings regarding the TVT-O, Ms. Sutphin’s implant surgery, and her initiation of this lawsuit.” Pl.’s Mem. of Law in Supp. of Resp. in Opp’n, 13 [ECF No. 32]. “Retroactivity is not favored in the law.” *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). And courts generally do

not construe congressional enactments to have a retroactive effect unless their language explicitly requires that result. *Id.* But the case here deals with a common law doctrine that was later codified by statute. Because the learned intermediary doctrine already applied to medical device cases in West Virginia, prior to the enactment of West Virginia Code § 55-7-30, I find the doctrine applies in this case. *See Tyree*, 56 F. Supp. 3d at 832. However, summary judgment on the issue is inappropriate.

Defendant argues that Ethicon had no duty to warn pelvic floor surgeons of the risks known that are within the common knowledge of that group. Ethicon further argues that all the injuries Ms. Sutphin alleges are within the category of risks known to be common to pelvic floor surgery.

I find a dispute of material fact as to whether, as a group, pelvic floor surgeons already knew of certain risks associated with the TVT-O because of their professional knowledge as physicians. And therefore, I cannot find as a matter of law that Defendant did not have a duty to warn Plaintiff's physician. Furthermore, Plaintiff's general expert, Dr. Daniel Elliott, opines that Ethicon failed to disclose numerous adverse risks, safety information, and warnings associated with the product to physicians that should have been included in the product's Instructions for Use ("IFU"). Rule 26 Expert Report of Dr. Daniel Elliott, Ex. 10, 37–40 [ECF No 31–2]. Plaintiff's general expert, Dr. Bruce Rosenzweig, opines that "Ethicon failed to inform physicians or patients about potential for degradation of the mesh and the complications that could follow." Rule 26 Expert Report of Bruce Rosenzweig, M.D.

Ex. 11, 23 [ECF No. 31–3]. Dr. Afram, Plaintiff’s treating physician, testified in his deposition that after reviewing the IFU, he remained unaware of specific health risks associated with the TVT-O product. *See* Dep. of David Afram, M.D., Ex. 13, 78–79 [ECF No. 31–4]. Plaintiff therefore provides sufficient evidence to create a question for the jury of whether Ethicon’s warnings to Plaintiff’s physician, Dr. Afram, were adequate. Defendant’s Motion for Summary Judgment on Plaintiff’s claim for strict liability failure to warn (Count III) is **DENIED**.

c. Negligence (Count I)

To prove negligence, a plaintiff must establish (1) duty, (2) breach, (3) causation, and (4) damages. *See Hersh v. E-T Enters., Ltd.*, 752 S.E.2d 336, 341 (W. Va. 2013). To establish a claim for negligent design, a plaintiff must show that a manufacturer failed “to conform to the design standards of a reasonably prudent manufacturer” in designing its product. *See Mullins*, 117 F. Supp. 3d at 812–13. Claims made under a theory of strict liability are distinct from those made under a theory of negligence. *Id.* (citing *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 613 (W. Va. 1983)). “Unlike in strict liability, where the defective condition of the product is the principal basis of liability, negligence focuses on the conduct of the manufacturer.” *Mullins*, 236 F. Supp. at 944 (citing *Morningstar*, 253 S.E.2d at 667, Syl. pt. 3).

First, Defendant requests I reconsider the holding in *Mullins* and find that a negligence theory of products liability requires a plaintiff to provide evidence of an alternative feasible design. I decline to do so. Because negligence focuses on manufacturer conduct, rather than solely on the product at issue, the elements of

proof are different than those required in a strict liability claim. I reiterate my reasoning in *Mullins* that “the existence of an alternative, feasible design is relevant to the manufacturer’s conduct, but a requirement to establish an alternative, feasible design is simply not among the requisite elements under a negligence products liability theory.” *Id.*

Second, Defendant argues that even if proof of an alternative design is not required, Plaintiff fails to meet the elements of negligence. Viewing the evidence in the light most favorable to Plaintiff, I disagree. Plaintiff offers sufficient evidence in this case to create a dispute of material fact as to whether Ethicon conformed to the design standards of a reasonably prudent manufacturer in designing TVT-O. *See* Rule 26 Expert Report of Dr. Daniel Elliott, Ex. 10, 37–41 [ECF No 31–2]; Rule 26 Expert Report of Bruce Rosenzweig, M.D. Ex. 11, 59, 102–105 [ECF No. 31–3]; Expert Report of Michael Thomas Margolis, M.D. Ex. 12 [ECF No. 31–4]. Defendant’s Motion for Summary Judgement is therefore **DENIED** on Count I for negligence.

d. All remaining claims

Plaintiff does not intend to proceed on the following claims alleged in her Short Form Complaint at trial: strict liability–manufacturing defect (Count II); strict liability–defective product (Count IV); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); and

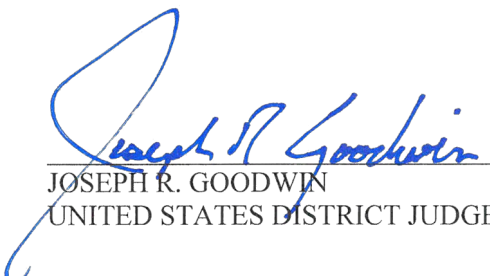
unjust enrichment (Count XV). Pl.'s Response in Opp. to Def.'s Mot. for Summ. J. [ECF No. 31]. Accordingly, Defendant's Motion for Summary Judgment on these claims is **DENIED as moot**.

IV. Conclusion

The court **DENIES** Defendant's Motion for Summary Judgment [ECF No. 25] on the following claims: negligence (Count I); strict liability–failure to warn (Count III); strict liability–design defect (Count V). The court further **DENIES as moot** Defendant's Motion for Summary Judgment [ECF No. 25] on the following claims: strict liability–manufacturing defect (Count II); strict liability–defective product (Count IV); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); and unjust enrichment (Count XV).

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 15, 2020



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE